



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61M 39/12, 5/162, 5/145, A61J 1/00	A1	(11) International Publication Number: WO 00/25852 (43) International Publication Date: 11 May 2000 (11.05.00)
(21) International Application Number: PCT/US99/25413 (22) International Filing Date: 28 October 1999 (28.10.99) (30) Priority Data: 60/106,237 29 October 1998 (29.10.98) US (71) Applicant: MINIMED INC. [US/US]; 12744 San Fernando Road, Sylmar, CA 91342 (US). (72) Inventors: ADAIR, Randy, W.; 27969 Skycrest Circle, Valencia, CA 91354 (US). MOBERG, Sheldon; 11828 Paso Robles Avenue, Granada Hills, CA 91344 (US). SRISATHAPAT, Chalirak; 8701 Vinevalley Drive, Sun Valley, CA 91352 (US). (74) Agent: KOVELMAN, Paul, H.; MiniMed, Inc., 12744 San Fernando Road, Sylmar, CA 91342 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: RESERVOIR CONNECTOR (57) Abstract <p>A method and apparatus for a connection interface between a reservoir or syringe, infusion set tubing, and an infusion pump is provided. A base is provided which is adapted to receive a reservoir. The base has a base engagement member, such as a detent, projecting therefrom. A cap is provided which is adapted to receive the base. The cap includes a first cap engagement member, such as a detent opening, which is adapted to removably engage the base detent. The cap further includes a second cap detent opening which is adapted to removably engage the base detent. A piercing member, such as a needle, is disposed in the interior of the cap in such a manner that the needle is separated from the reservoir septum when the base detent is in the first cap detent opening, and the needle pierces the reservoir septum when the base detent is in the second cap detent opening. When the reservoir, the base and the cap are connected to form an integrated unit, this unit is then capable of being inserted and secured in the infusion pump housing.</p> <div data-bbox="857 1171 1377 1948"> </div>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

5

RESERVOIR CONNECTOR

This claims priority from provisional patent application no. 60/106,237 which was filed on October 29, 1998 and U.S. patent application no. 09/xxx,xxx (attorney docket 0059-0307) filed October 28, 1999, which are specifically incorporated herein by reference.

BACKGROUND OF THE INVENTION1. Field of the Invention

This invention relates generally to improvements in syringe and reservoir interfaces for use in infusion pumps such as those used for controlled delivery of medication to a patient. More specifically, this invention relates to an improved connection interface between a reservoir or syringe, infusion set tubing, and an infusion pump.

2. Description of the Related Art

Infusion pump devices and systems are relatively well-known in the medical arts, for use in delivering or dispensing a prescribed medication such as insulin to a patient. In one form, such devices comprise a relatively compact pump housing adapted to receive a syringe or reservoir carrying a prescribed medication for administration to the patient through infusion tubing and an associated catheter.

The infusion pump includes a small drive motor connected via a lead screw assembly for motor-driven advancement of a reservoir piston to administer the medication to the user. Programmable controls are normally provided for operating the drive motor continuously or at periodic intervals to obtain a closely controlled and accurate delivery of the medication over an extended period of time. Such infusion pumps are utilized to administer insulin and other medications, with exemplary pump constructions being shown and described in U.S. Patent Nos. 4,562,751; 4,678,408; 4,685,903; 5,080,653 and 5,097,122, which are incorporated by reference herein.

Infusion pumps of the general type described above have provided significant advantages and benefits with respect to accurate delivery of medication or other fluids over an extended period of time. The infusion pump can be designed to be relatively compact as well as water resistant, and may thus be adapted to be carried by the user, for example, by means of a belt clip. As a result, important medication can be delivered to the user with

5 precision and in an automated manner, without significant restriction on the user's mobility or life-style, including the ability to participate in water sports.

Infusion sets refer to the tubing and connection apparatus which provide a path for the medication to flow from the reservoir or syringe located in the pump to the user. The connectors for attaching the infusion set tubing to the reservoirs can take various forms. A
10 luer connection is a commonly used connection method. Nevertheless, it remains desirable to develop improved designs of connection methods to facilitate infusion procedures and to provide suitable interface connections which are water resistant so as to permit a user to participate in water sports.

15 SUMMARY OF THE PREFERRED EMBODIMENTS

An apparatus for connecting a reservoir having a septum and a base to a conduit, such as infusion set tubing, is provided. In certain aspects of the present invention, the apparatus comprises a cap and a releasable coupler which is adapted to releasably couple
20 the base to the cap in one of two positions. A piercing member, such as a needle, is coupled to the conduit. The needle is disposed in the cap in a position other than the interior of the reservoir when the base is in the first position. The needle is further disposed to pierce the reservoir septum when the base is in the second position.

In another embodiment, the apparatus is used for connecting a reservoir having a
25 septum and a base to a housing as well as to a conduit. The housing has a housing engagement member, such as a thread. The apparatus comprises a cap and a releasable coupler which is adapted to releasably couple the base to the cap in one of two positions. A piercing member, such as a needle, is releasably coupled to the conduit. The needle is disposed in the cap in a position other than the interior of the reservoir when the base is in
30 the first position. The needle is further disposed to pierce the reservoir septum when the base is in the second position. The cap further includes an engagement member, such as a thread, which is adapted to engage with the housing engagement member.

In another embodiment, the cap further includes a vent port which is covered with hydrophobic material. This permits air to pass through the cap while preventing water
35 from doing so.

5 BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded, perspective view of a medication reservoir connection interface apparatus.

FIG. 2 is a perspective view of a cap used as a medication reservoir connection interface apparatus.

10 FIG. 3 is an exploded, perspective view of an alternative embodiment of a medication reservoir connection interface apparatus.

FIG. 4 is a side, cut-away view of a cap used as a medication reservoir connection interface apparatus.

15 FIG. 5 is a side, plan cut-away view of a medication reservoir connection interface apparatus with a needle inserted into a reservoir.

FIG. 6 is a side, plan cut-away view of a medication reservoir connection interface apparatus which is inserted into a pump housing.

FIG. 7 is a perspective view of an alternative embodiment of a medication reservoir connection interface apparatus.

20 FIG. 8 is a perspective top view of an alternative embodiment of a medication reservoir connection interface apparatus which is secured into a pump housing.

FIG. 9 is a perspective view of an alternative embodiment of a medication reservoir connection interface apparatus.

25 FIG. 10 is an exploded, perspective view of a cap used as a medication reservoir connection interface apparatus.

FIG. 11 is a perspective view of a medication reservoir connection interface adapter.

FIG. 12 is a cross-sectional view of a medication reservoir connection interface adapter.

30 FIG. 13 is a perspective view of an alternative embodiment of a cap used as a medication reservoir connection interface apparatus.

FIGs. 14a - 14c are cross-sectional views of various embodiments of venting ports for use with a reservoir connection interface apparatus or adapter.

5

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the following description, reference is made to the accompanying drawings which form a part hereof and which illustrate several embodiments of the present invention. It is understood that other embodiments may be utilized and structural and operational changes may be made without departing from the scope of the present invention.

As shown in the drawings for purposes of illustration, the invention is embodied in an interface for connecting a syringe or a medication reservoir to a conduit, such as infusion set tubing or an external needle, as well as to an infusion pump. In a one embodiment, a base is provided which is adapted to receive a reservoir. A cap is provided which is adapted to be releasably coupled to the base in one of two positions. The releasable coupler comprises a pair of detents projecting from the base and two pairs of detent openings in the cap which are adapted to removably engage the base detents.

A piercing member, such as a needle, is disposed in the interior of the cap in such a manner that the needle is separated from the reservoir septum when the base detents are in the first pair of cap detent openings, and the needle pierces the reservoir septum when the base detents are in the second pair of cap detent openings. When the reservoir, the base and the cap are connected, an integrated unit is formed which is then capable of being inserted in the infusion pump housing. Engagement members, such as threads, for the cap and the pump housing are used to secure the integrated unit in the housing.

FIGs. 1 and 2 show an infusion set connector interface for attachment to a medication reservoir. The connector interface is comprised of a base 2 and a cap 4. The cap 4 includes a needle 9 located internal to the cap housing. FIG. 1 is an exploded view, and therefore, the base 2 would normally be fixedly attached to a reservoir 1 by securing it around the swage 3. However, alternative embodiments of the present invention include a removable base so that the connector interface could be used with standard reservoirs, cartridges or syringes which were not initially manufactured with the base attached.

The cap 4 portion of the connector interface is removably attached to the base 2 with a releasable coupler. In one embodiment, the releasable coupler is comprised of detents formed on the base 2 and detent openings disposed in the cap 4. Two detents 8 are disposed on the sides of the base 2 and are spaced 180 ° radially apart. Only one detent 8 is shown in FIG. 1. The detents 8 are sized to fit in the two lower detent openings 6, or

5 alternatively, in the two upper detent openings 7 which are formed in the cap 4. As with the pair of detents 8, each of the lower detent openings 6 and each of the upper detent openings 7, respectively, are radially spaced apart by 180 °.

In operation, the base 2 and the reservoir 1 form an integrated unit which in turn is to be connected to the cap 4. In connecting this integrated base/reservoir unit to the cap 4,
10 the base 2 is inserted into the lower end of the cap 4 until the detents 8 snap into the lower detent openings 6. This is accomplished by moving the detents 8 over internal cam surfaces 10 toward the lower detent openings 6. The cam surfaces act as ramps which compress the detents 8 sufficiently to permit them to snap into the lower detent openings 6. Internal threads 10a guide the detents 8 into position.

15 When the base/reservoir unit is in this first, lower position, the needle 9 is positioned apart from the septum (not shown) of the reservoir 1. Thus the needle does not pierce the septum while the base/reservoir unit is in this first position. When the base/reservoir unit is connected to the cap in this fashion, an integrated cap/base/reservoir unit is thereby formed. Such an integrated cap/base/reservoir unit can be sold or stored for
20 long periods of time in this fashion. Alternatively the end user could assemble this unit shortly prior to placing it in the pump for use.

When the user desires to insert the cap/base/reservoir unit in the pump housing and commence dispensing the medication through a conduit, such as insertion set tubing 5, the base 2 is moved to the second position within the cap 4. This is accomplished by twisting
25 the base /reservoir unit while pushing it further into the cap 4. The detents 8 disengage from the lower detent openings 6 and engage into the upper detent openings 7. Additional internal threads 10a of the cap 4 serve to guide the detents 8 over additional cam surfaces 10 from their first position in the lower detent openings 6 to the second position in the upper detent openings 7.

30 In one embodiment, the threads and the spacing between the lower detents 6 and the upper detents 7 is such that a one quarter (1/4) turn of the base will cause the base/reservoir unit to travel from the first to the second position. The needle 9 is disposed so that when the base/reservoir unit is in the second position, the needle pierces the septum of the reservoir 1. Thus the movement of the base/reservoir unit from the first to the
35 second position within the cap serves to cause the needle to pierce the reservoir's septum, thus permitting the fluid in the reservoir to flow into the needle 9 and the insertion set tubing 5.

5 After this connection is made, the reservoir, base and cap form a unit which can be releasably secured in the housing of a medication infusion pump. (not shown) Detents 4a extend radially from the exterior of the cap and are adapted to engage into detent openings (not shown) in the pump housing. In an alternative embodiment, the cap 4 can include external threads (not shown) which are used to engage the threads of the pump housing in
10 order to secure the reservoir/base/cap unit into the housing.

FIGs. 3 and 4 show an alternative embodiment of the infusion set connector interface. The connector interface is comprised of a base 11 and a cap 12. The cap 12 includes a needle 18 located internal to the cap housing (FIG. 4). The base 11 would normally be fixedly attached to the reservoir 1 by securing it around the swage 3.
15 However, alternative embodiments of the present invention include a removable base so that the connector interface could be used with standard reservoirs, cartridges or syringes which were not initially manufactured with the base attached.

The cap 12 portion of the connector interface is removably attached to the base 11 with a releasable coupler. In this embodiment, the releasable coupler is comprised of
20 detents formed on the base 11 and detent openings disposed in the cap 12. Two detents 13 are disposed on the sides of the base 11 and are spaced 180 ° radially apart. Only one detent 13 is shown in FIG. 3. The detents 13 are sized to fit in two detent openings 14 which are formed in the cap 12. As with the pair of detents 13, each of the detent openings 14 are radially spaced apart by 180 °.

25 In operation, the base 11 and the reservoir 1 form an integrated unit which in turn is to be connected to the cap 12. In connecting this integrated base/reservoir unit to the cap 12, the base 11 is inserted into the lower end of the cap 12. The detents 13 slide into matingly shaped and longitudinally open entry slots 15 formed within the interior walls of the cap 12. When the base 11 is fully inserted in the cap 12, the leading edges of the
30 detents 13 abut an annular stop shoulder 16 formed within the cap 12. After the detents 13 are in this position, the base 11 is rotated within the cap 12 toward a locked position. Referring to FIG. 4, this rotation displaces the detents 13 in a rotational direction for engagement with cam surfaces 17 formed within the cap 12. The rotational force on the detents 13 over the cam surfaces 17 provides a compression force on the detents 13.
35 Continued rotation of the base 11 displaces the detents 13 past the cam surfaces 17 and into alignment with the detent openings 14. The detents 13 enter the detent openings 14 with a snap-action. Thus, the detents 13 are effectively locked within the detent openings

5 14 to prevent longitudinal separation of the base 11 from the cap 12.

In the preferred embodiment, the internal needle 18 of the cap 12 is disposed so that when the base/reservoir unit is fully inserted in the cap 12, the needle pierces the septum (not shown) of the reservoir 1. Thus the insertion force of the base/reservoir unit to the point where the detents 13 abut the annular stop shoulder 16 causes the needle 18 to
10 pierce the septum, thus permitting the fluid in the reservoir to flow into the needle 18 and the insertion set tubing (not shown).

After this connection is made, the reservoir, base and cap form a unit which can be releasably secured in the housing of a medication infusion pump. (not shown) The cap 12 includes external threads 19 which are used to engage the threads of the pump housing in
15 order to secure the reservoir/base/cap unit into the housing. In the preferred embodiment, the threads 19 have an eight threads per inch ("TPI"), 2 start profile. Moreover, they have a square shaped cross section which maximizes their holding strength. Other thread profiles and cross-sections may be used however.

When disconnection of the base 11 from the cap 12 is desired, the base 11 must be
20 reverse-rotated within the cap 12, to move the detents 13 past the cam surfaces 17 into re-alignment with the entry slots 15. Such reverse-rotation of the coupler can be performed relatively easily, but essentially requires an affirmative intent by the user to disconnect the coupling. When the detents 13 are re-aligned with the entry slots 15, the cap 12 and base 11 can be separated easily with minimal longitudinal force.

25 FIG. 5 shows a cross sectional view of the reservoir/base/cap integrated unit in accordance with the embodiment of FIGs. 3 and 4. The reservoir 1 includes a crimp seal swage 3 which encloses the outer periphery of the rubber septum 20 in order to secure the septum 20 to the reservoir 1 and form a water tight seal. With the base 11 in the locked position as shown, the detents 13 of the base 11 are locked into the detent openings 14 to
30 securely attach the base/reservoir unit into the cap 12. The needle 18 pierces the rubber septum 20, thus permitting the flow of liquid through the needle 18 and into the infusion set tubing cavity 22. Infusion set tubing (not shown) is secured into the cavity 22 to allow the liquid to continue its flow to the user.

In the preferred embodiment, the conduit from the cap 12 is infusion set tubing.
35 However in an alternative embodiment, the conduit comprises a second needle (not shown). This is secured into the cavity 22 with the point of the second needle extending outward. With this arrangement, the connector serves as an apparatus for permitting the

5 refilling of the reservoir 1. The second, external needle would pierce the septum of a supply vial of fluid. The fluid could then be drawn into the cap in a reverse flow and into the reservoir 1 via the internal needle 18.

10 In the embodiment shown in FIG. 5, infusion set tubing is secured to the cavity 22 to allow liquid to flow to the user. The cavity 22 is disposed in the raised portion of the cap 12. In an alternative embodiment, however, the raised portion of the cap 12 can be in the shape of a standard luer fitting 47 shown in FIG. 13.

15 Referring to FIG. 5, in one embodiment the base 11 is formed around and fixedly attached to the crimp seal swage 3 portion of the reservoir 1. In an alternative embodiment, however, the base 11 is not fixedly attached to the reservoir. Rather, the base 11 is a separate unit which is adapted to be releasably secured to the reservoir via a friction fit. This arrangement permits the connector apparatus to be used with standard reservoirs.

20 Still referring to FIG. 5, the cap 12 includes threads 19 for securing the assembly into the pump housing (not shown). A shoulder 23 is formed as part of the cap 12 and is adapted to seat against the pump housing to form a water tight seal. This prevents any water which is exterior to the housing from entering, thus permitting the user to engage in water sports.

25 The construction of these pumps to be water resistant can give rise to operational problems. As the user engages in activities which expose the pump to varying atmospheric pressures, such as for example, swimming or traveling in an air plane, differential pressures can arise between the interior of the air tight/water-resistant housing and the atmosphere. Should the pressure in the housing exceed external atmospheric pressure, the resulting forces could cause the reservoir piston to be driven inward thus delivering unwanted medication. Alternatively, should the pressure in the housing be less than the external pressure, the resulting forces could cause the infusion pump motor to work harder to advance the reservoir piston.

35 To address this problem, a preferred embodiment of the invention includes a vent which permits water resistant housing construction. The cap 12 includes a plurality of vent ports 24, only one of which is shown in FIG. 5. The vent ports 24 permit equalization of pump housing pressure to atmospheric pressure. Hydrophobic material (not shown) covers the interior openings of the vent ports 24. Hydrophobic material permits air to pass through the material while preventing water or other liquids from doing

5 so, thus permitting water resistant venting. The preferred embodiment uses a hydrophobic material such as Gore-Tex® , PTFE, HDPE, or UHMW polymers from sources such as W.I. Gore & Associates, Flagstaff, AZ, Porex Technologies, Fairburn, GA, DeWAL Industries, Saunderstown, RI, or Pall Specialty Materials, Port Washington, N.Y.

10 These materials are available in sheet form or molded (press and sintered) in a geometry of choice. Referring to FIGs 14a - 14c, preferred methods to attach this material to the cap 12 include molding the hydrophobic material into a sphere 50 (FIG. 14a) or a cylinder 51 (FIG. 14b) and pressing it into a cavity in the pre-molded plastic housing. Alternatively, a label 52 (FIG. 14c) of this material could be made with either a transfer adhesive or heat bond material 53 so that the label could be applied over the vent port 24.

15 Alternatively, the label could be sonically welded to the housing. In either method, air will be able to pass freely, but water will not.

In an alternative embodiment which is not shown, the venting is accomplished through a vent port located in the pump housing. This is described in greater detail in copending application Serial No. _____, filed concurrently herewith (Attorney Docket

20 No. 0059-0286), which application is incorporated by reference in its entirety. Alternatively, vent ports can be placed both in the cap 12 as well as the pump housing.

An advantage of placing the vent port and hydrophobic material in the cap 12, as opposed to in the pump housing only, is that the infusion set and its related connectors are disposable and are replaced frequently with each new reservoir or vial of medication.

25 Thus, new hydrophobic material is frequently placed into service. This provides enhanced ventilation as compared with the placement of hydrophobic material in only the pump housing. Material in this location will not be replaced as often and thus is subject to dirt or oil build up which will retard ventilation.

As an alternative to the use of hydrophobic material, water can be prevented from

30 flowing through the vent port by other apparatuses, such as the use of relief valves.

FIG. 6 shows a cross-sectional view of the reservoir/base/cap unit in accordance with the embodiment of FIGs. 3 and 4 which is secured into a pump housing 30. The threads 19 of the cap 12 engage the pump housing threads. Rather than the use of threads, an alternative embodiment (not shown) of the cap 12 could include detents extending

35 radially from the exterior of the cap 12 which are adapted to engage detent openings in the pump housing.

The shoulder 23 portion of the cap 12 seats against the pump housing 30 to permit

5 water tight construction. Further aiding in the water tight construction is an O-ring seal 31 which is disposed in the pump housing 30 and located just above the shoulder 23. In the preferred embodiment, the vent material 32 is comprised of hydrophobic material and is sonic welded to the upper interior surface of the cap 12. Alternatively, the vent material 32 could be attached to the cap 12 with an adhesive. The vent ports are not shown in FIG.
10 6.

Although the foregoing description of the venting was in connection with the embodiment of FIGs 3 - 6, this feature is also applicable to the embodiment of FIGs 1 - 2.

FIGs. 7 and 8 show an alternative embodiment of the cap 12. Referring to FIG. 7, a cap engagement member consists of a detent arm 34 which is formed in the upper
15 portion of the cap 12. The purpose of the detent arm 34 is to securely engage the cap 12 into the pump housing. FIG. 8 shows a top view of the cap 12 positioned in the pump housing 30. The pump housing 30 has two case lock recesses 35 disposed in the circular rim of the housing. The detent arm 34 snaps into either of the case lock recesses 35. This engagement results in a "click" when the cap 12 is appropriately seated, thus providing
20 both tactile and audible feedback to the user that the cap is securely engaged in the pump housing. Moreover, the detent arm 34 aligning with the recess 35 also serves as a visual indicator that the cap 12 is appropriately seated.

FIG. 9 shows an alternative embodiment of the cap 12 which contains a child safety feature. The cap 12 includes a locking member which consists of a safety tab 36
25 disposed in a groove 37. The safety tab 36 is sized such that it is able to slide along the length of the groove 37. When the safety tab 36 is in the position shown in FIG. 9, the detent arm 34 is unable to retract from its engaged position. Thus when the cap 12 is seated into the pump housing 30 (not shown) and the detent arm is seated into the case lock recess 35 (not shown), the safety tab 36 will prevent the detent arm 34 from
30 disengaging from the case lock recess 35 thus more securely locking the cap 12 in the pump housing.

Thus for example, a parent could slide the safety tab 36 from the unlocked location in the groove 37 to the locked location shown in FIG. 9 so that it would be more difficult for a young child or infant to inadvertently remove the cap/base/reservoir unit from the
35 pump housing. On the other hand, when the safety tab 36 is moved to the opposite end of the groove 37, the detent arm 34 is able to retract thus permitting removal of the cap 12 from the pump housing.

5 Although the foregoing description of the cap engagement member and child safety tab was in connection with the embodiment of FIGs 3 - 9, this feature is also applicable to the embodiment of FIGs 1 - 2.

FIG. 10 shows an exploded view of the cap 12 and the vent material 32. In the preferred embodiment, the vent material is made of hydrophobic material and is formed in
10 a circular shape with a circular hole in the center. The vent material 32 is attached to the upper interior surface 38 of the cap 12 via sonic welding or an adhesive. When it is so attached, the needle 18 protrudes through the center hole of the vent material 32 but the interior openings of the vent ports 24 (not shown) are covered.

FIGs. 11 and 12 show an embodiment of the present invention where an adapter 40
15 is provided to allow a standard style syringe 41 with an integrated luer fitting 42 to be mounted and sealed in the pump housing. The syringe 41 is inserted through the center of the adapter 40 and held into place by a friction fit. The O-ring seal 43 in the adapter 40 seats against the syringe wall in order to prevent water and dirt from entering the pump housing.

20 A shoulder 45 is formed as part of the adapter 40 and is adapted to seat against the interior of the pump housing to form a water tight seal. Two tabs 44 are formed on the top surface of the adapter 40 and provide a surface for the user to grip the adapter 40 and twist it so that the adapter threads 19 engage the threads (not shown) of the pump housing. A detent arm 34 is formed in the upper portion of the adapter 40. Its purpose is to securely
25 lock the adapter 40 into the pump housing (not shown) in the same manner as is shown in FIG. 8. Although not shown in FIGs. 11 and 12, the adapter 40 can further contain vent ports covered with hydrophobic material or a relief valve in order to permit water resistant venting of the pump housing in the same manner as previously described with other embodiments.

30 FIG. 13 shows another embodiment of the present invention where an interface is provided to connect a reservoir to a conduit, such as tubing, via a standard luer fitting connection. This allows a luer style disposable infusion set to connect to the pump housing (not shown). A cap 46 is formed with a luer fitting 47 portion as an integral part thereof. Except for the shape of the luer fitting 47 portion, the cap 46 has all of the other
35 features of the cap 12 shown in FIG. 5. Thus referring to FIG. 13, the cap 46 is comprised of, among other things, threads 19, detent openings 14, a shoulder 23, vent ports 24, a detent arm 34, and a needle (not shown) disposed in the interior of the cap 46.

- 5 While the description above refers to particular embodiments of the present invention, it will be understood that many modifications may be made without departing from the spirit thereof. The accompanying claims are intended to cover such modifications as would fall within the true scope and spirit of the present invention. The presently disclosed embodiments are therefore to be considered in all respects as
- 10 illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

5 WHAT IS CLAIMED IS:

1. An apparatus for connecting a reservoir having a septum and a base to a conduit, the apparatus comprising:

a cap;

10 a releasable coupler adapted to releasably couple the base with the cap in one of a first and a second position; and

a piercing member coupled to the conduit, said piercing member disposed in the cap in a position other than the interior of the reservoir when the base is in the first position, the piercing member disposed to pierce the reservoir
15 septum when the base is in the second position.

2. The apparatus of claim 1 further comprising a vent port in the cap, the vent port covered with hydrophobic material.

20 3. An apparatus for connecting a reservoir having a septum and a base to a conduit and to a housing having a housing engagement member, said apparatus comprising:

a cap;

a releasable coupler adapted to releasably couple the base with the cap in one of a
25 first and a second position;

a piercing member coupled to the conduit, said piercing member disposed in the cap in a position other than the interior of the reservoir when the base is in the first position, the piercing member disposed to pierce the reservoir septum when the base is in the second position; and

30 a cap engagement member disposed on the cap, the cap engagement member adapted to engage the housing engagement member.

4. The apparatus of claim 3 wherein the cap further comprises a second cap engagement member adapted to engage the housing.

5 5. The apparatus of claim 4 wherein the cap further comprises a locking member having two positions, the locking member adapted to prevent movement of the second cap engagement member when the locking member is in the first position and to permit the movement of the second cap engagement member when the locking member is in the second position.

10

6. The apparatus of claim 3 further comprising a vent port in the cap, the vent port covered with a hydrophobic material.

7. The apparatus of claim 3 wherein the cap further comprises means for
15 venting the housing to the atmosphere without permitting liquids to pass through the venting means.

8. The apparatus of claim 3 wherein the cap further comprises a shoulder adapted to sealingly engage the housing.

20

9. An apparatus for connecting a reservoir having a septum to a conduit and to a housing having a first thread member, the apparatus comprising:

a base adapted to receive the reservoir;

a detent tab projecting from the base;

25 a cap adapted to receive the base, said cap having a first detent opening adapted to removably engage the base detent tab and a second detent opening adapted to removably engage the base detent tab;

a piercing member coupled to the conduit, said piercing member disposed in the cap in a position other than the interior of the reservoir when the base detent tab is engaged in the first detent opening and said piercing member disposed to pierce the reservoir septum when the base detent tab is engaged in the second detent opening; and

30

a second thread member disposed on the cap, the second thread member adapted to engage the first thread member.

- 5 10. A method of connecting a reservoir having a septum and a base to a conduit, the method comprising:
- inserting the base into a cap having a piercing member and a coupler, the piercing member coupled to the conduit, and the coupler adapted to releasably couple the base with the cap in one of a first and a second position;
- 10 releasably coupling the base to the first position in the cap whereby the piercing member is disposed in a position other than the interior of the reservoir; and
- releasably coupling the base to the second position in the cap whereby the piercing member is disposed to pierce the septum.
- 15 11. The method of claim 10 wherein the cap further comprises a second releasable coupler, said method further comprising:
- coupling the reservoir, the base and the cap to a housing whereby the second releasable coupler releasably engages with the housing.
- 20 12. The method of claim 11 further comprising venting the housing through a vent port in the cap, said vent port containing hydrophobic material.
13. The method of claim 10 wherein the cap further comprises a cap engagement member adapted to engage the exterior of a housing.
- 25 14. The method of claim 13 wherein the cap further comprises a locking member having two positions, the locking member adapted to prevent movement of the cap engagement member when the locking member is in the first position and to permit the movement of the cap engagement member when the locking member is in the second
- 30 position.

5 15. A method of connecting a reservoir to a housing and to a conduit, said reservoir having a septum and a base with a detent tab, and said housing having a first thread member, the method comprising:

 inserting the base to a first detent position in a cap having a piercing member coupled to the conduit and a second thread member, whereby the piercing
10 member is disposed to be at a position other than the interior of the reservoir;

 inserting the base to a second detent position in the cap whereby the piercing member is disposed to pierce the reservoir septum; and
 connecting the reservoir, the base and the cap to the housing whereby the second
15 thread member engages with the first thread member.

 16. An apparatus for connecting a reservoir having a septum and a base to a conduit, said apparatus comprising:
 a cap adapted to receive the base;
20 means in the cap for piercing the septum;
 means for removably coupling the base with the cap in one of a first and a second position whereby the piercing means does not pierce the septum when the base is in the first position and whereby the piercing means pierces the septum when the base is in the second position; and
25 means for coupling the piercing means with the conduit.

 17. The apparatus of claim 16 further comprising means for permitting air to flow through an opening in the cap without permitting liquids to pass through the opening.

- 5 18. An apparatus for connecting a reservoir having a septum and a base to a housing and to a conduit, said apparatus comprising:
- a cap adapted to receive the base;
- means in the cap for piercing the septum;
- means for removably coupling the base with the cap in one of a first and a second
- 10 position whereby the piercing means does not pierce the septum when the base is in the first position and whereby the piercing means pierces the septum when the base is in the second position;
- means for coupling the piercing means with the conduit; and
- means for removably engaging the cap with the housing.
- 15 19. The apparatus of claim 18 wherein the cap further comprises means for securing the cap to the housing whereby an audible indication is given when the cap is secured to the housing.
- 20 20. The apparatus of claim 18 wherein the cap further comprises means for securing the cap to the housing whereby a visual indication is given when the cap is secured to the housing.
- 25 21. The apparatus of claim 18 wherein the cap further comprises means for securing the cap to the housing whereby a tactile indication is given when the cap is secured to the housing.
22. The apparatus of claim 19 wherein the cap further comprises locking means for preventing movement of the securing means.
- 30 23. The apparatus of claim 20 wherein the cap further comprises locking means for preventing movement of the securing means.
24. The apparatus of claim 18 wherein the cap further comprises means for
- 35 securing the cap to the housing whereby water is prevented from entering the housing.

- 5 25. An apparatus for connecting a reservoir having a septum to a conduit, said
conduit coupled to a piercing member disposed in a cap, the apparatus comprising:
a base adapted to receive the reservoir and to be received by the cap;
a releasable coupler adapted to releasably couple the base and the reservoir with the
cap in one of a first and a second position; and
10 said releasable coupler adapted to position the septum whereby the piercing
member is in a position other than the interior of the reservoir when the
base and reservoir are in the first position, and to position the septum to be
pierced by the piercing member when the base and the reservoir are in the
second position.
- 15 26. An apparatus for connecting a reservoir having a septum to a conduit, said
conduit coupled to a piercing member disposed in a cap, said cap having a
first detent opening and a second detent opening, the apparatus comprising:
a base adapted to receive the reservoir and to be received by the cap;
20 a detent tab projecting from the base, said detent tab adapted to removably engage
one of the first detent opening and the second detent opening; and
said detente tab disposed on the base to position the septum whereby the piercing
member is in a position other than the interior of the reservoir when the
detent tab is engaged in the first detent opening and to position the septum
25 to be pierced by the piercing member when the base detent tab is engaged
in the second detent opening.
27. An apparatus for connecting a reservoir having a septum and a base to a
conduit, the apparatus comprising:
30 a cap adapted to receive the base;
a releasable coupler adapted to releasably couple the base with the cap; and
a piercing member coupled to the conduit, said piercing member disposed to pierce
the reservoir septum when the base is inserted into the cap.
- 35 28. The apparatus of claim 27 further comprising a vent port in the cap, the
vent port covered with hydrophobic material.

5 29. An apparatus for connecting a reservoir having a septum and a base to a
conduit and to a housing having a housing engagement member, said apparatus
comprising:
 a cap adapted to receive the base;
 a releasable coupler adapted to releasably couple the base with the cap;
10 a piercing member coupled to the conduit, said piercing member disposed to pierce
 the reservoir septum when the base is inserted in the cap; and
 a cap engagement member disposed on the cap, the cap engagement member
 adapted to engage the housing engagement member.

15 30. The apparatus of claim 29 wherein the cap further comprises a second cap
engagement member adapted to engage the housing.

 31. The apparatus of claim 30 wherein the cap further comprises a locking
member having two positions, the locking member adapted to prevent movement of the
20 second cap engagement member when the locking member is in the first position and to
permit the movement of the second cap engagement member when the locking member is
in the second position.

 32. The apparatus of claim 29 further comprising a vent port in the cap, the
25 vent port covered with a hydrophobic material.

 33. The apparatus of claim 29 wherein the cap further comprises means for
venting the housing to the atmosphere without permitting liquids to pass through the
venting means.

30

 34. The apparatus of claim 29 wherein the cap further comprises a shoulder
adapted to sealingly engage the housing.

5 35. An apparatus for connecting a reservoir having a septum to a conduit and
to a housing having a first thread member, the apparatus comprising:
a base adapted to receive the reservoir;
a detent tab projecting from the base;
a cap adapted to receive the base, said cap having a longitudinal entry slot adapted
10 to receive the detent tab;
an annular stop shoulder disposed in the cap at the distal end of the entry slot to
prevent further longitudinal movement of the detent tab;
said cap having a detent opening formed adjacent to the annular stop shoulder and
adapted to removably engage the detent tab;
15 a cam surface disposed between the distal end of the entry slot and the detent
opening to permit the detent tab to travel from the distal end of the entry
slot and to engage the detent opening;
a piercing member coupled to the conduit, said piercing member disposed in the
cap to pierce the reservoir septum when the base and reservoir are inserted
20 in the cap; and
a second thread member disposed on the cap, the second thread member adapted to
engage the first thread member.

25 36. A method of connecting a reservoir having a septum and a base to a
conduit, the method comprising:
inserting the base and reservoir into a cap having a piercing member and a coupler,
the piercing member coupled to the conduit, and the coupler adapted to
releasably couple the base with the cap;
piercing the septum with the piercing member; and
30 releasably coupling the base to the cap.

37. The method of claim 36 wherein the cap further comprises a second
releasable coupler, said method further comprising:
coupling the reservoir, the base and the cap to a housing whereby the second
35 releasable coupler releasably engages with the housing.

5 38. The method of claim 37 further comprising venting the housing through a vent port in the cap, said vent port containing hydrophobic material.

 39. The method of claim 37 wherein the cap further comprises a cap engagement member adapted to engage the exterior of the housing.

10

 40. The method of claim 39 wherein the cap further comprises a locking member having two positions, the locking member adapted to prevent movement of the cap engagement member when the locking member is in the first position and to permit the movement of the cap engagement member when the locking member is in the second position.

15

 41. A method of connecting a reservoir to a housing and to a conduit, said reservoir having a septum and a base with a detent tab, and said housing having a first thread member, the method comprising:

20

inserting the base and reservoir into a cap having

- (i) a piercing member coupled to the conduit;
- (ii) a longitudinal entry slot adapted to receive the detent tab;
- (iii) an annular stop shoulder disposed at the distal end of the entry slot to prevent further longitudinal movement of the detent tab;
- (iv) a detent opening formed adjacent to the annular stop shoulder and adapted to removably engage the detent tab; and
- (v) a cam surface disposed between the distal end of the entry slot and the detent opening to permit the detent tab to travel from the distal end of the entry slot and to engage the detent opening;

25

30

sliding the base and reservoir in the cap until the detent tab abuts the annular stop shoulder;

piercing the septum with the piercing member;

twisting the base and reservoir inside the cap until the detent tab releasably engages with the detent opening by traveling over the cam surface; and

35

connecting the reservoir, the base and the cap to the housing whereby the second thread member engages with the first thread member.

5 42. An apparatus for connecting a reservoir having a septum and a base to a
conduit, said apparatus comprising:
 a cap adapted to receive the base;
 means in the cap for piercing the septum;
 means for removably coupling the base and the reservoir with the cap whereby the
10 piercing means pierces the septum when the base and reservoir are coupled
 to the cap; and
 means for coupling the piercing means with the conduit.

 43. The apparatus of claim 42 further comprising means for permitting air to
15 flow through an opening in the cap without permitting liquids to pass through the opening.

 44. An apparatus for connecting a reservoir having a septum and a base to a
housing and to a conduit, said apparatus comprising:
 a cap adapted to receive the base;
20 means in the cap for piercing the septum;
 means for removably coupling the base and the reservoir with the cap whereby the
 piercing means pierces the septum when the base and reservoir are coupled
 to the cap;
 means for coupling the piercing means with the conduit; and
25 means for removably engaging the cap with the housing.

 45. The apparatus of claim 44 wherein the cap further comprises means for
securing the cap to the housing whereby an audible indication is given when the cap is
secured to the housing.

30 46. The apparatus of claim 44 wherein the cap further comprises means for
securing the cap to the housing whereby a visual indication is given when the cap is
secured to the housing.

35 47. The apparatus of claim 44 wherein the cap further comprises means for
securing the cap to the housing whereby a tactile indication is given when the cap is
secured to the housing.

5 48. The apparatus of claim 45 wherein the cap further comprises locking means
for preventing movement of the securing means.

 49. The apparatus of claim 46 wherein the cap further comprises locking means
for preventing movement of the securing means.

10

 50. The apparatus of claim 44 wherein the cap further comprises means for
securing the cap to the housing whereby water is prevented from entering the housing.

 51. An apparatus for connecting a reservoir having a septum to a conduit, said
15 conduit coupled to a piercing member disposed in a cap, the apparatus comprising:
a base adapted to receive the reservoir and to be received by the cap;
a releasable coupler adapted to releasably couple the base with the cap; and
said releasable coupler adapted to position the septum to be pierced by the piercing
member when the base and reservoir is inserted into the cap.

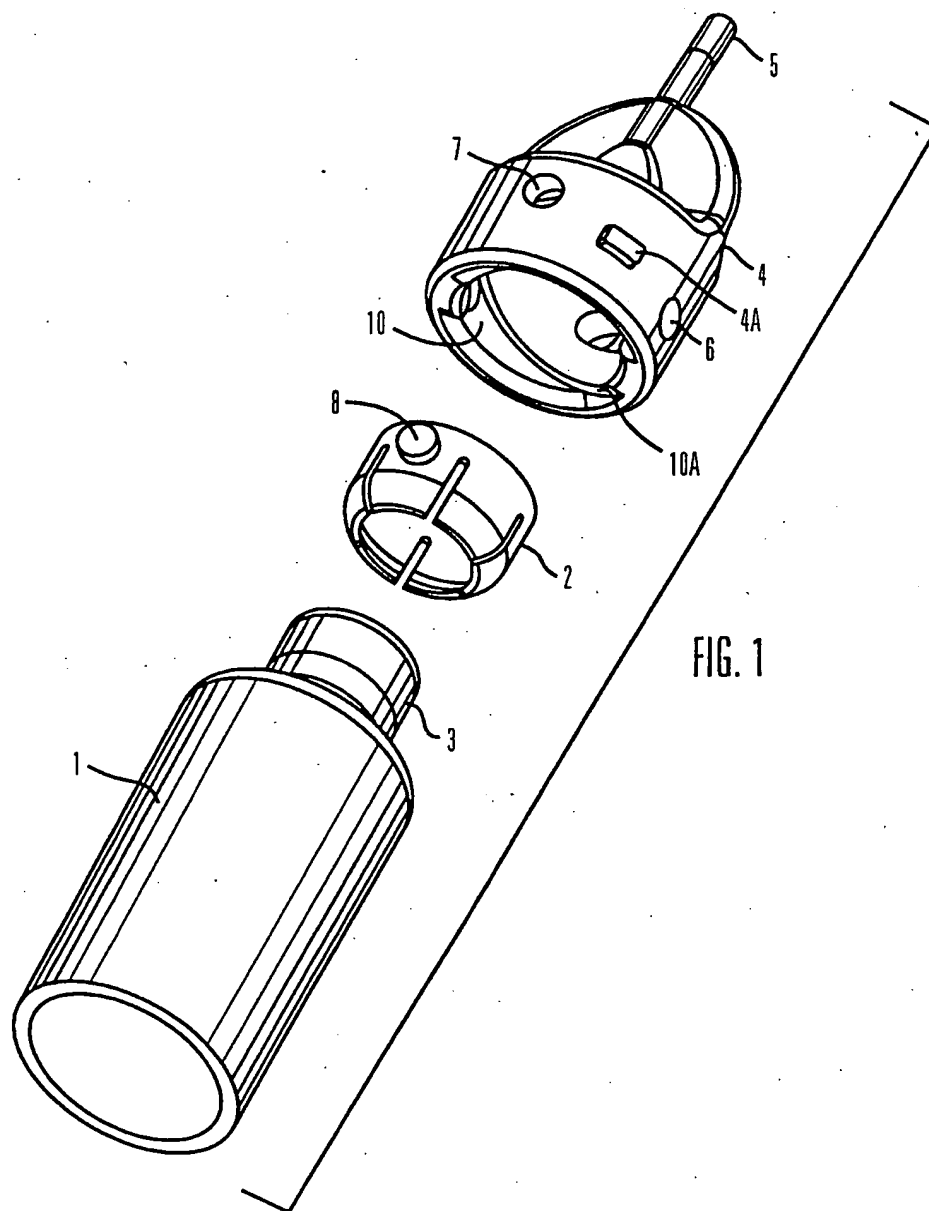
5 52. An apparatus for connecting a reservoir having a septum to a conduit, said
 conduit coupled to a piercing member disposed in a cap, said cap having a
 longitudinal entry slot, an annular stop shoulder disposed at the distal end
 of the entry slot, a detent opening formed adjacent to the annular stop
10 shoulder, a cam surface disposed between the distal end of the entry slot
 and the detent opening, the apparatus comprising:
 a base adapted to receive the reservoir and to be received by the cap;
 a detent tab projecting from the base, said detent tab adapted to slidably engage the
 entry slot until said detent tab abuts the annular stop shoulder;
 said detent tab adapted to removably engage the detent opening by traveling over
15 the cam surface; and
 said detent tab disposed on the base to position the septum to be pierced by the
 piercing member when the detent tab abuts the annular stop shoulder.

 53. An apparatus for connecting a syringe to a medication pump housing
20 having a first thread member, the apparatus comprising:
 an adapter having a substantially cylindrical shape;
 said adapter adapted to axially receive the syringe through the center of the
 adapter;
 a sealing member disposed in the adapter to sealingly engage the syringe;
25 a shoulder disposed on the adapter to sealingly engage the pump housing; and
 a second thread member disposed on the adapter, the second thread member
 adapted to engage the first thread member.

 54. The apparatus of claim 53 further comprising an engagement member
30 disposed on the adapter, said engagement member adapted to engage the exterior of the
 pump housing.

 55. The apparatus of claim 53 further comprising means disposed on the
 adapter for venting the pump housing to the atmosphere without permitting liquid to pass
35 through the venting means.

1/14



2/14

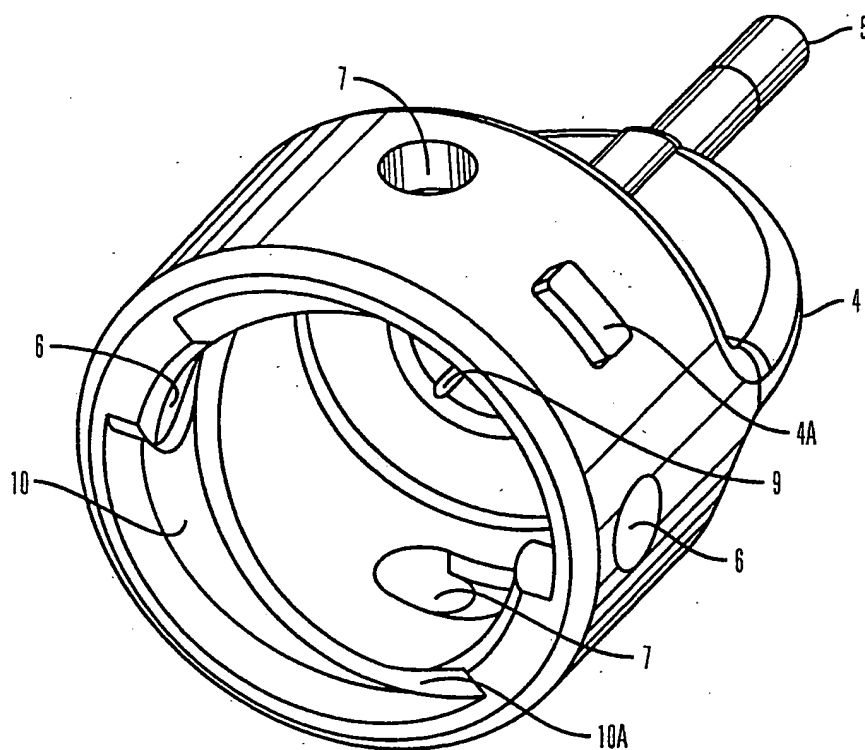


FIG. 2

3/14

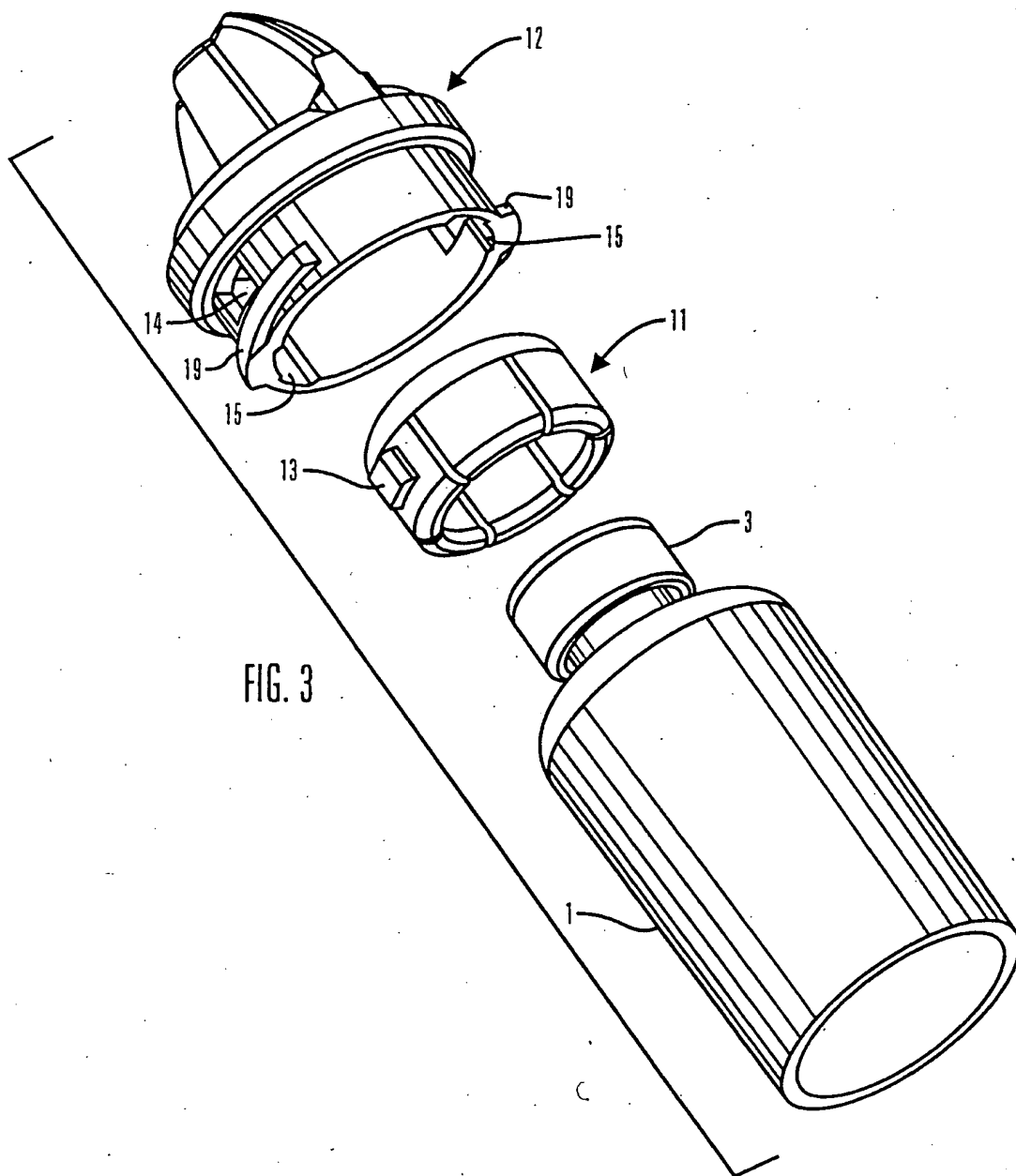


FIG. 3

4/14

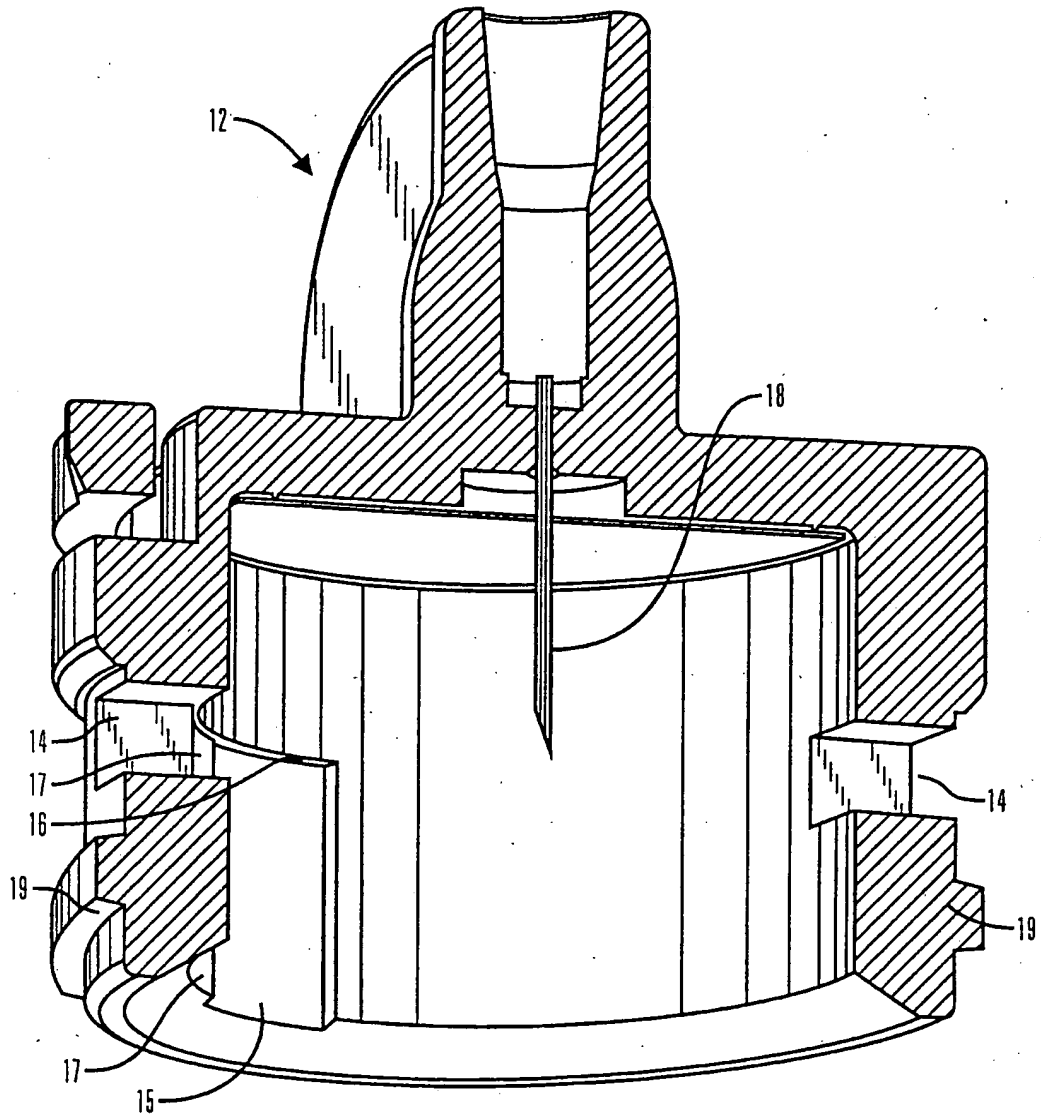
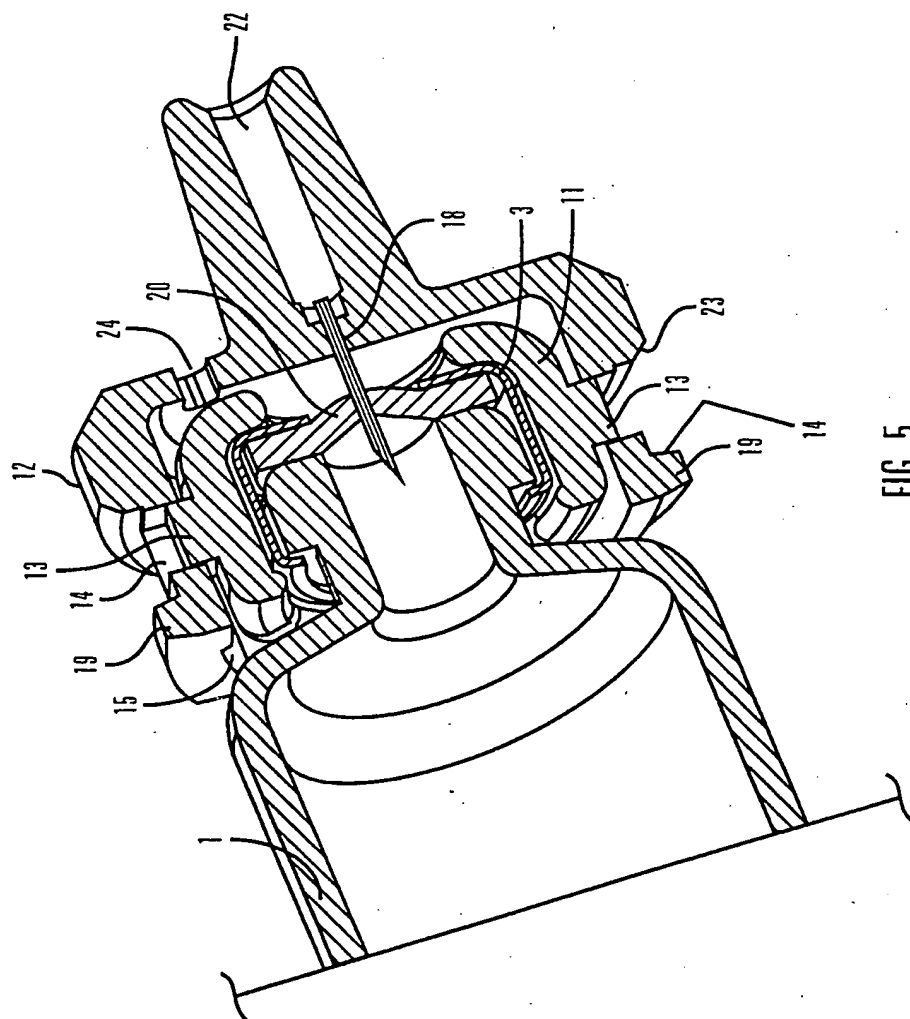
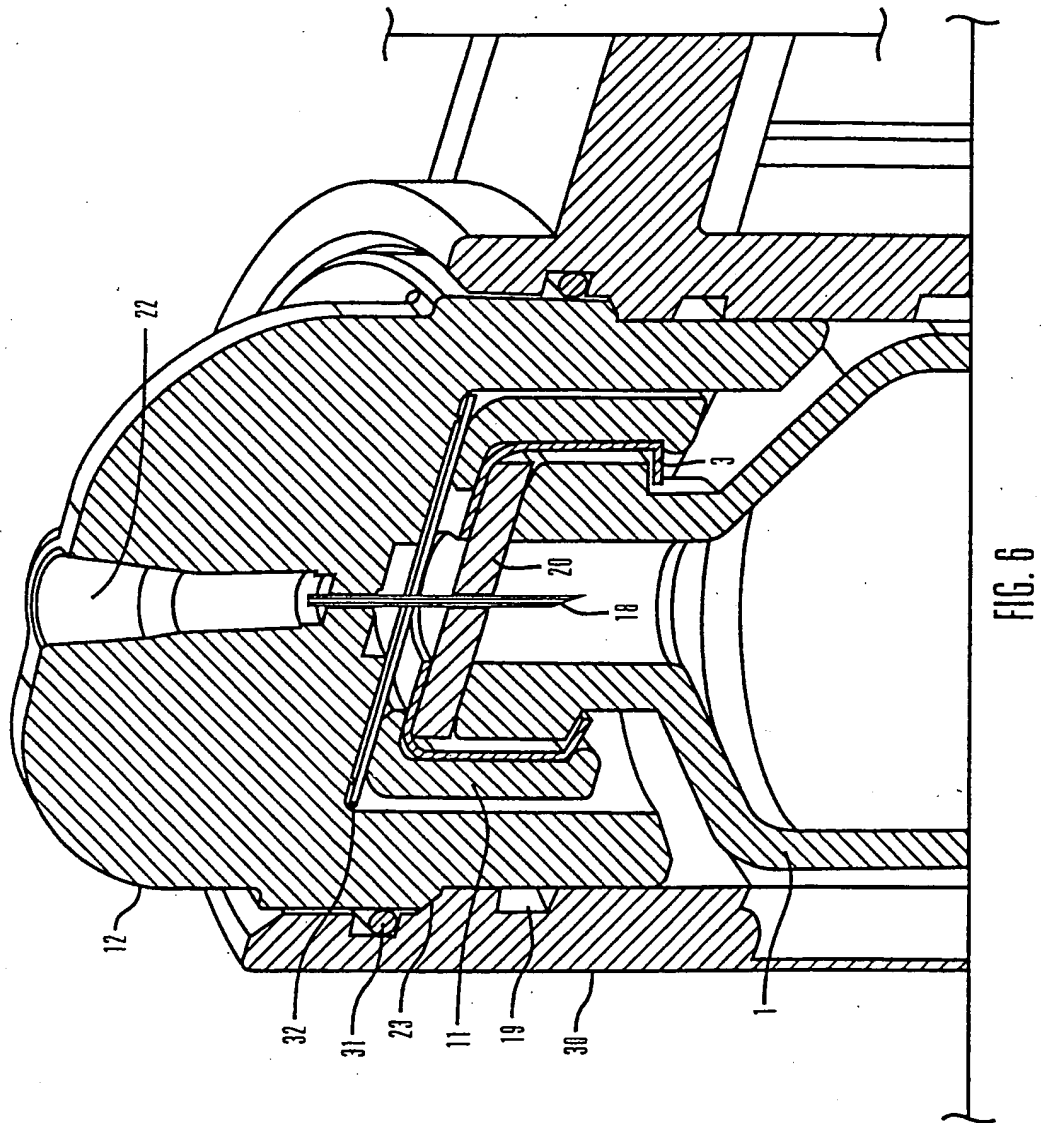


FIG. 4

5/14



6/14



7/14

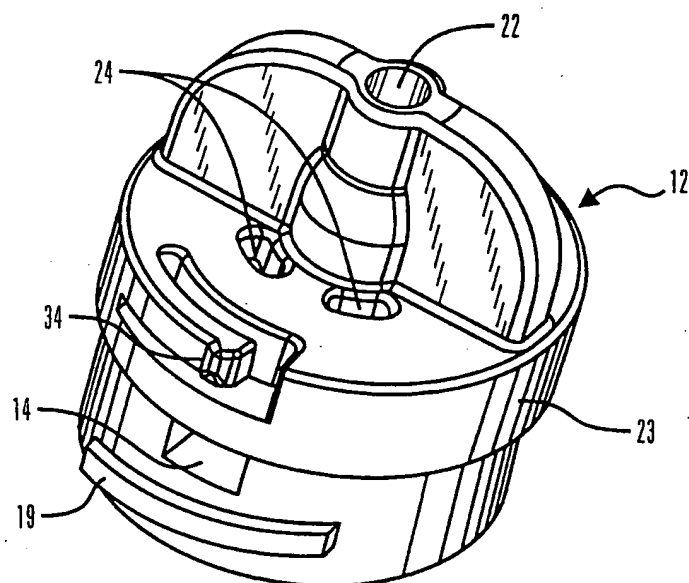


FIG. 7

8/14

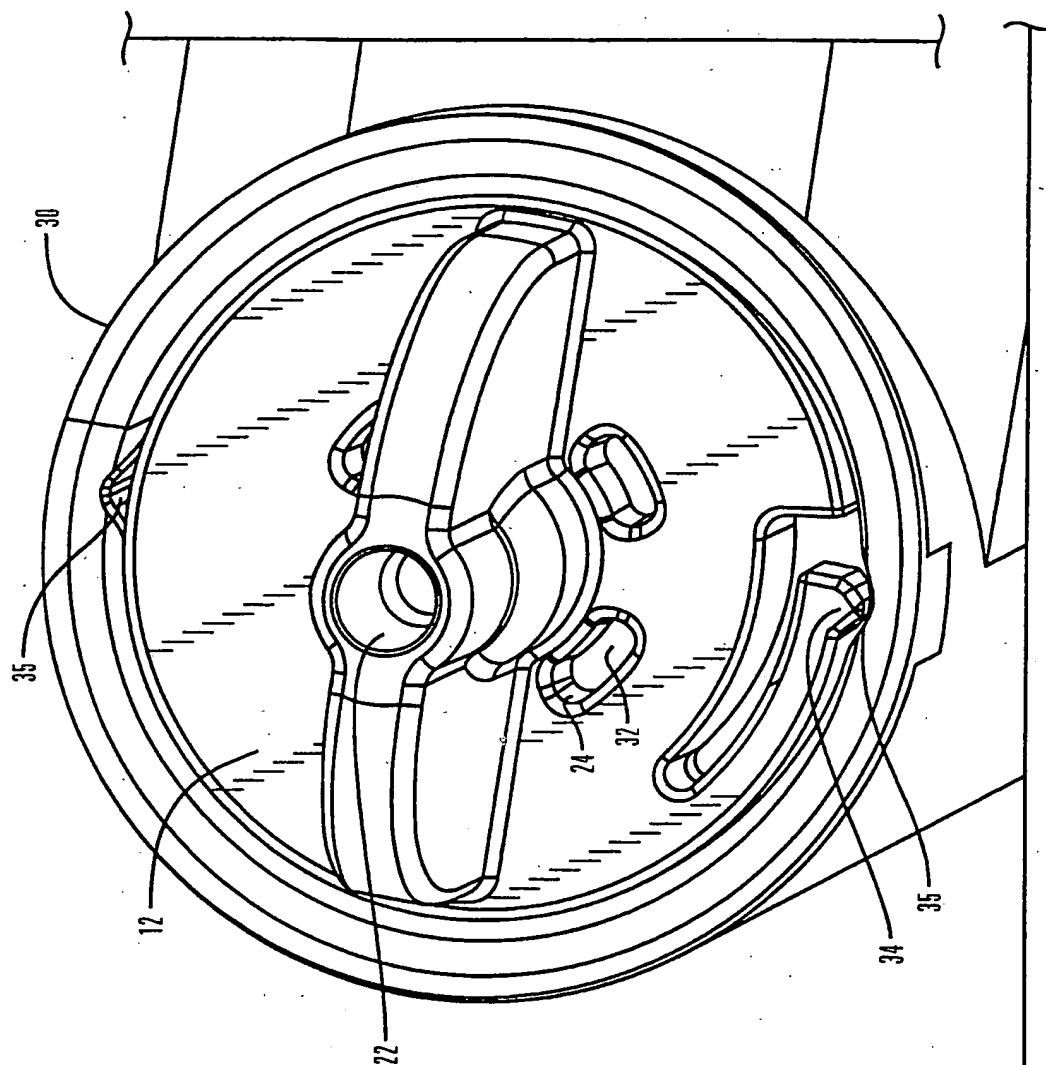


FIG. 8

9/14

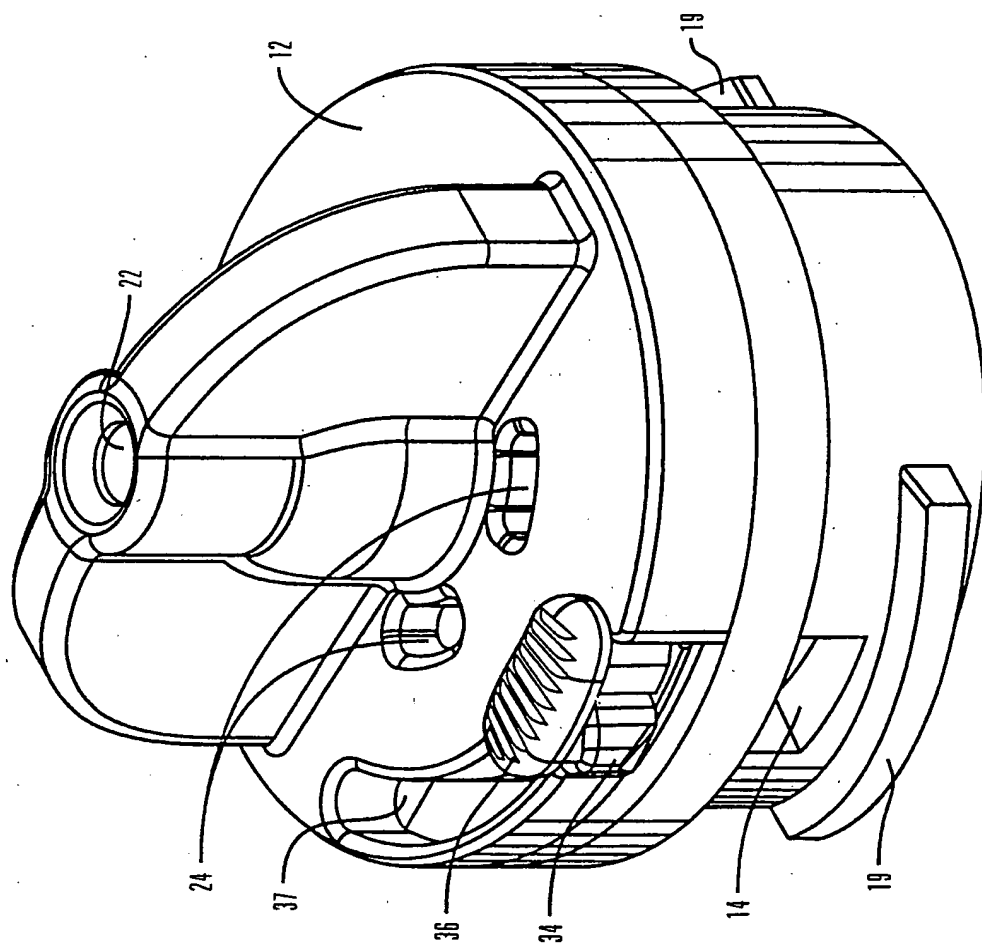


FIG. 9

9/14

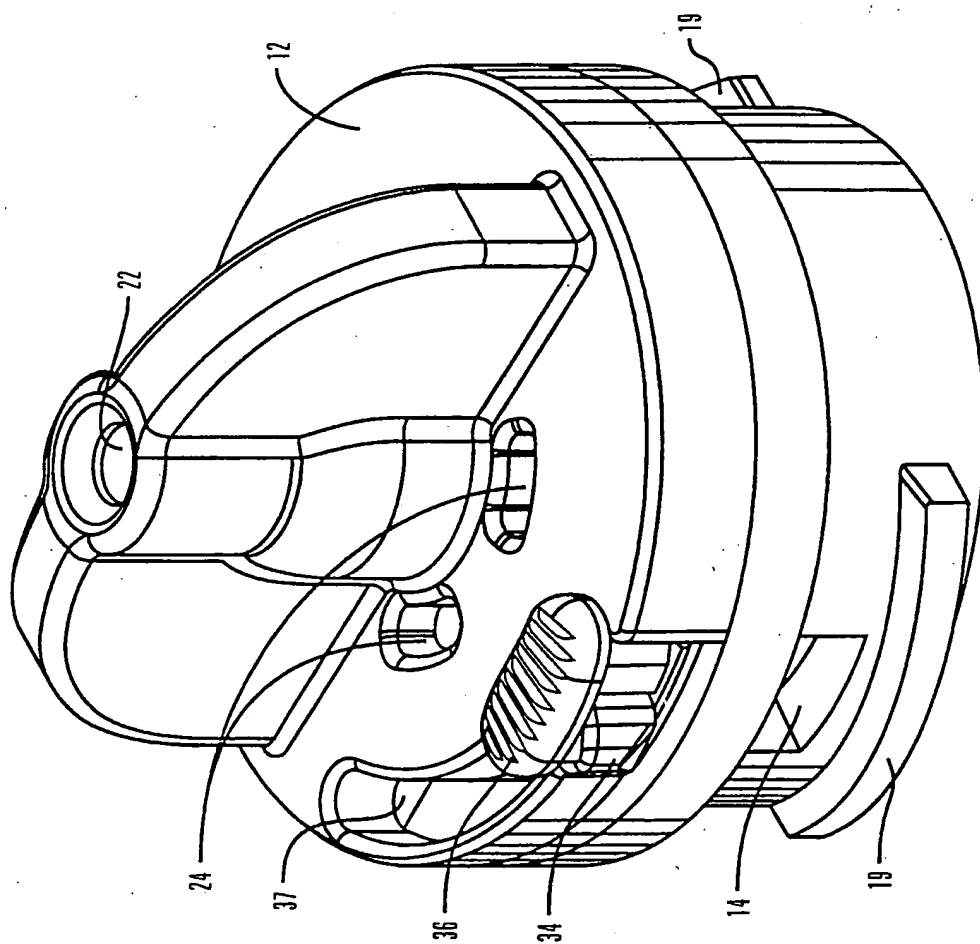


FIG. 9

10/14

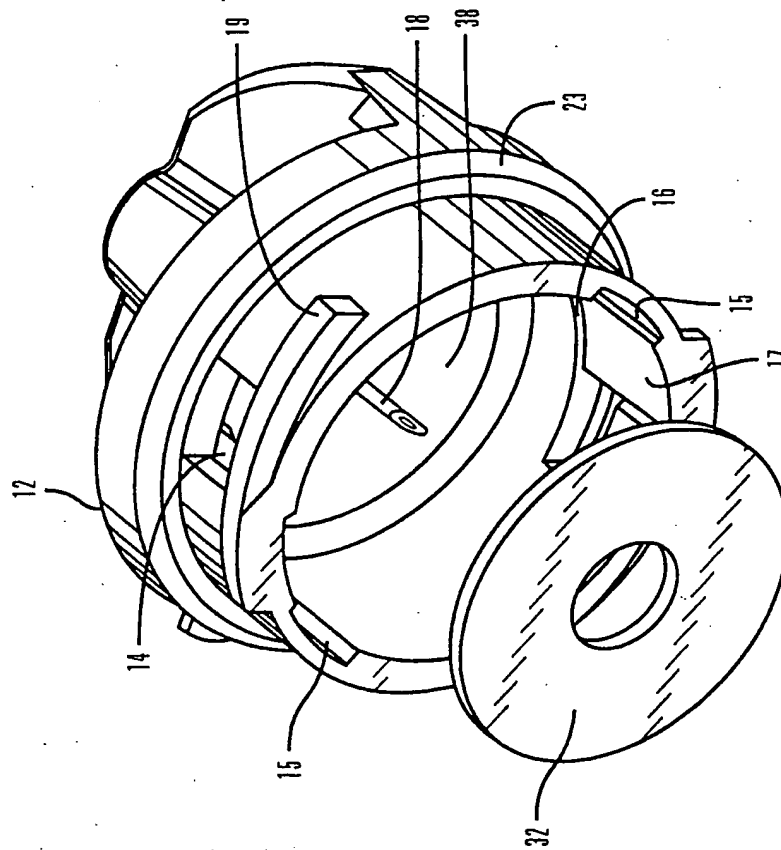


FIG. 10

11/14

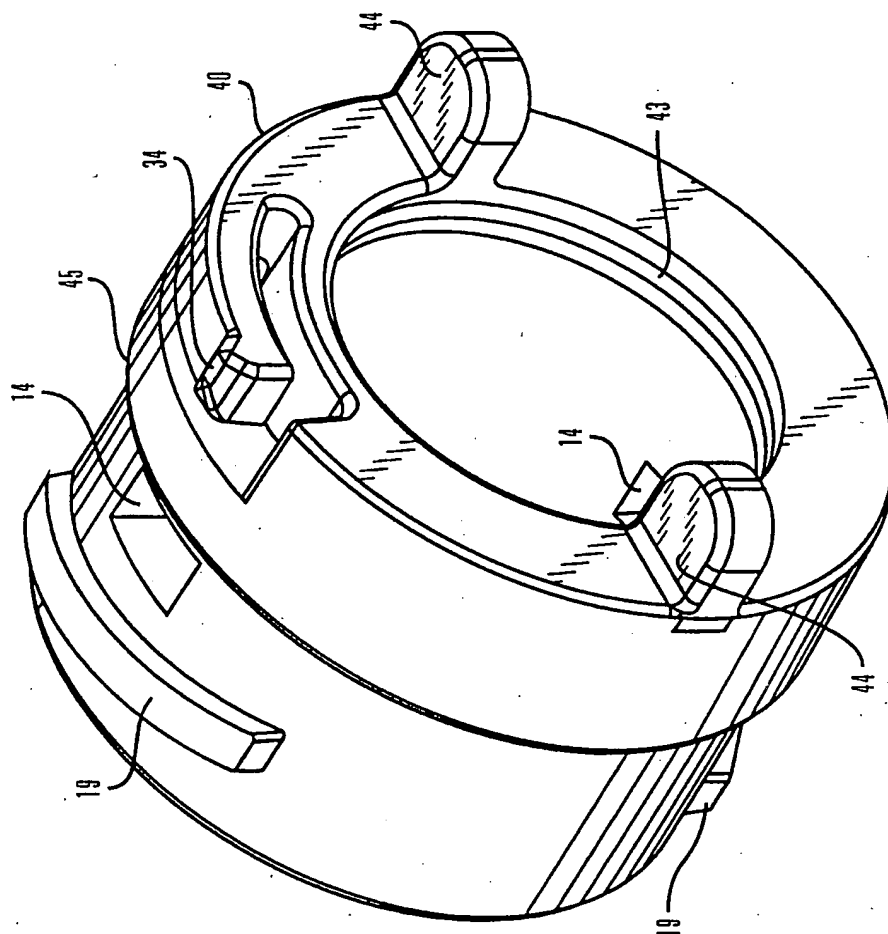


FIG. 11

12/14

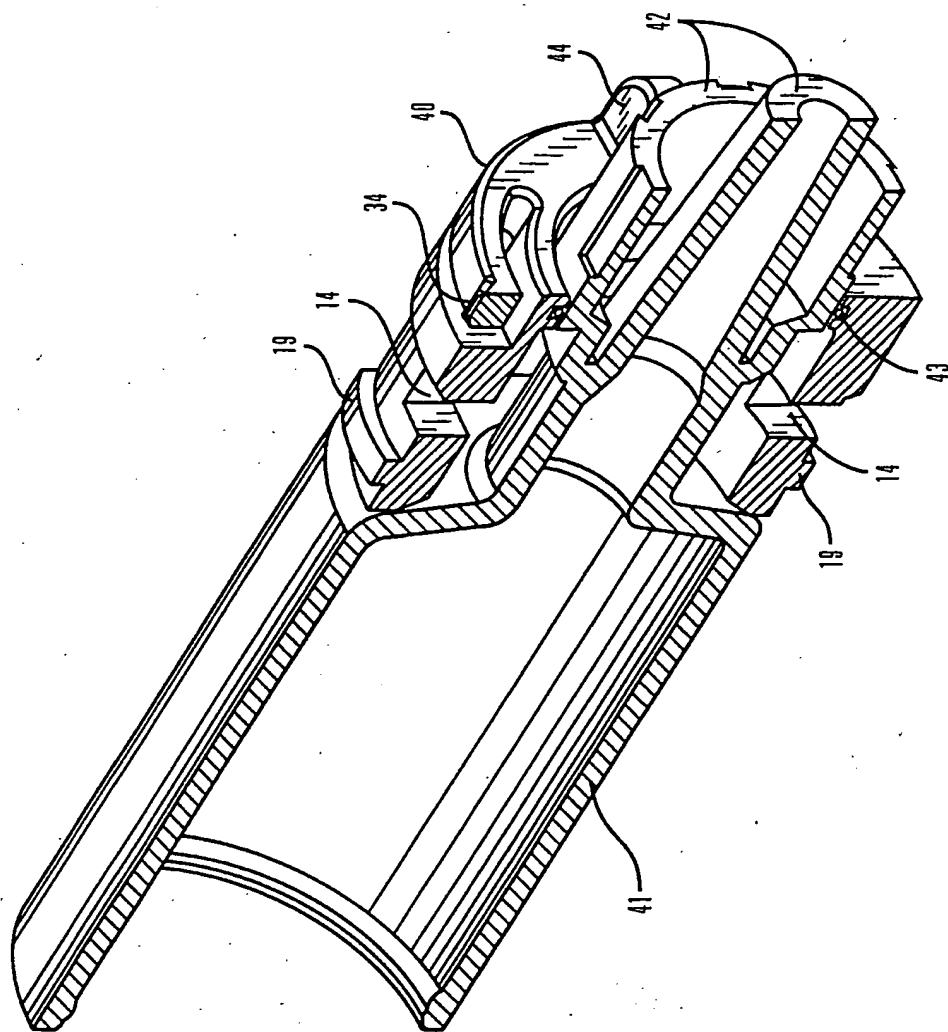


FIG. 12

13/14

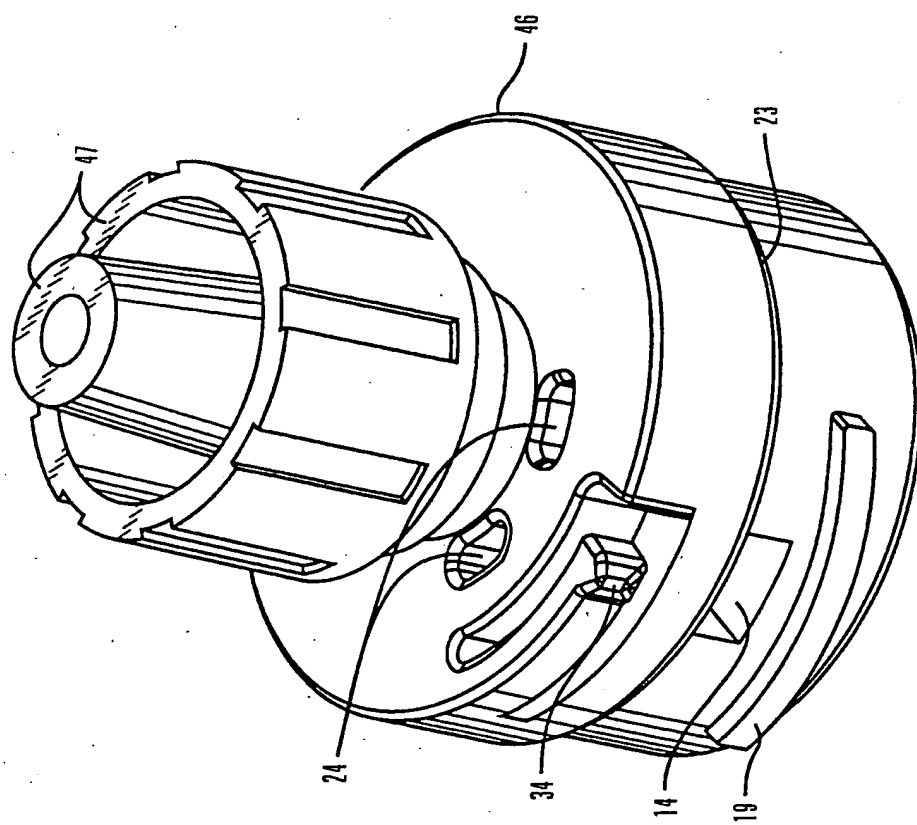


FIG. 13

14/14

FIG. 14a

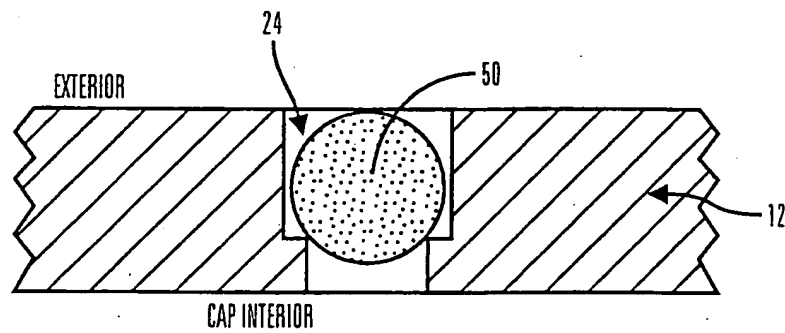


FIG. 14b

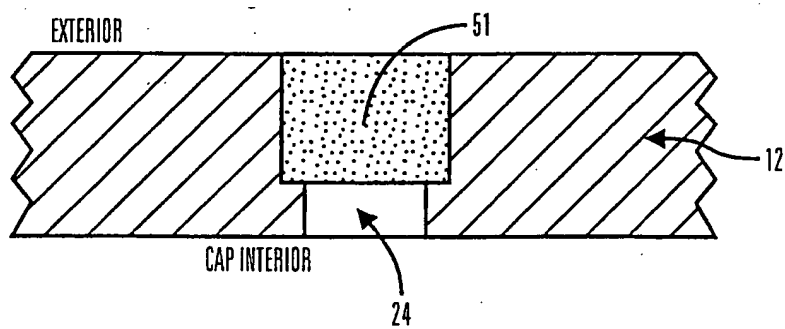
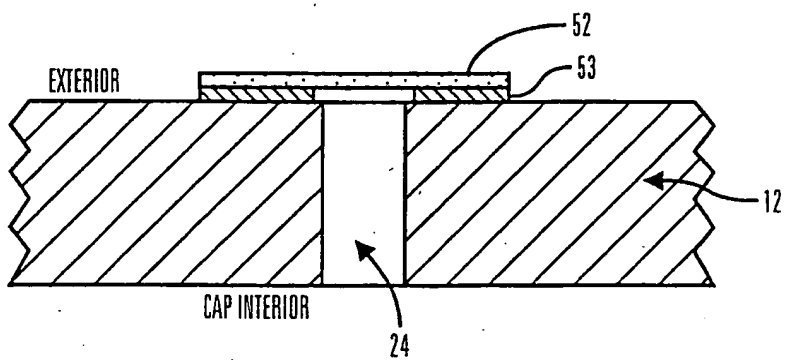


FIG. 14c



In: International Application No
PCT/US 99/25413

IPC 7 A61M39/12 A61M5/162 A61M5/145 A61J1/00

B. FIELDS SEARCHED

IPC 7 A61M A61J

Electronic data base consulted during the international search (name of data base and where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Relevant to claim No.

1, 2, 10,
15-17,
25-28,
36, 42,
43, 51

6, 7, 9,
12, 18,
32, 33,
35, 38,
41, 50, 53

☒ Patent family members are listed in annex.

*& document member of the same patent family

07.03.2000

Schönleben, J